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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/629,469	07/28/2000	Toshio Ota	084335-0123	3856

22428 7590 08/10/2004

FOLEY AND LARDNER  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9/4.

**Advisory Action**

**Application No.**

09/629,469

**Applicant(s)**

OTA ET AL.

**Examiner**

Carolyn L Smith

**Art Unit**

1631

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 28 July 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 28 July 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: 24,25 and 28.

Claim(s) rejected: 24-45.

Claim(s) withdrawn from consideration: 1,6,7,9,10,14,16,17 and 19-23.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 pages.
10. ☒ Other: See Continuation Sheet

Continuation of 2. NOTE: The proposed amendment will not be entered as the amended claims contain new issues that would require further search. The specification does not appear to provide proper support for the newly amended phrases in proposed amended claim 24 or 25 which is therefore considered NEW MATTER. Therefore, all of the objections and rejections are maintained. If the proposed amendment had been entered, the claim objections; 35 USC 112, first paragraph, Lack of Written Description rejections; and 35 USC 112, second paragraph rejections would have been removed. If the proposed amendment had been entered, the 35 USC 101 rejections; 35 USC 112, first paragraph (lack of enablement), rejections and 35 USC 102(e)(2) rejection would have been maintained.

35 USC 101 and 112, 1<sup>st</sup> paragraph (lack of enablement) rejections

Applicants recite a section of the MPEP (2107.01) stating an assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. This is acknowledged. Applicants state the MPEP states that when an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition, such a situation is sufficient to identify a specific utility for the invention (2107.01). This is acknowledged but Applicants have not provided scientifically sound correlative evidence in the instant application. Applicants state the specification discloses the elected clone is associated with diabetes with elevated expression compared to a control. This is found unpersuasive as it is unknown if such elevation is considered statistically significant. Applicants state HEMBA1004850 expression correlates with protein glycosylation, a complication associated with diabetes. This appears to be an assertion without factual support. Sound scientific evidence is requested to validate such assertions. Applicants cite a passage on page 407, lines 24-25. This is found unpersuasive as the specification appears to only have 284 pages. Because one skilled in the art would not know how to make and use the invention, the 35 USC 112, 1<sup>st</sup> paragraph rejection is also maintained.

35 USC 102(e)(2) rejection

Applicants state a disclosure cannot anticipate a claim, if the disclosure differs from the claimed invention. It is extremely rare that a prior art reference discloses the entirety of a claim, but rather an anticipatory reference reads on a claim due its disclosure of an embodiment specie within the metes and bounds of a claim, as is the case with the instant invention. Instant claim 28 does not specify if the coding region is an entire coding region or not. Therefore the terms "coding" and "region" in the claim have been broadly and reasonably interpreted wherein Shin et al. appears to anticipate the claim. This rejection is maintained.

Continuation of 10. Other: The references in the 1/16/04 IDS were lined through as they are duplicates of references from the 4/15/04 IDS.

*Adrian D. Marshall* 8/6/04  
Examiner, USPTO